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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/580,704	05/30/2000	George Peter Lomonossoff	DOW-04647	2167

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EXAMINER	
SANDALS, WILLIAM O	
ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 08/29/2002

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/580,704	Lomonossoff et al.
Examiner	**Art Unit**
William Sandals	1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jun 4, 2002*.

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-16* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Response to Arguments

1. Amendments to the specification in Paper No. 10, filed June 4, 2002 have overcome the objection to the specification in the previous office action, and the rejection is withdrawn.

2. Amendments to the claims in Paper No. 10 have overcome the rejection of the claims under 35 USC 112, second paragraph in the previous office action, and the rejection is withdrawn.

3. Arguments filed in Paper No. 10 regarding the rejection of the claims under 35 USC 102 have been fully considered but they are not persuasive. The response to the arguments is contained in the rejection repeated below.

4. Arguments filed in Paper No. 10 regarding the rejection of the claims under 35 USC 103(a) have been fully considered but are moot in view of the new grounds for rejection presented below.

5. Paper No. 10 states that a terminal disclaimer will be filed to overcome the double patenting rejection. The rejection is repeated below since no terminal disclaimer has been filed.

Claim Objections

6. Claims 4-6, 9 and 12-14 are objected to because of the following informalities: Each of the claims 4-6, 9 and 12-14 has been amended. The amended claims should be amended to insert the word "Amended" before each of claims 4-6, 9 and 12-14. Appropriate correction is required.

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 9-16 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of U. S. Patent No. 5,874,087. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant application claims a genus of a method of producing a modified plant virus while claims 1-9 of U. S. Patent No. 5,874,087 are drawn to a species of a method of producing a modified plant virus, and the species makes the genus obvious.

9. Claims 9-16 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 22-28 of U. S. Patent No. 5,958,422. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant application claims a genus of a method of producing a modified plant virus while claims 22-28 of U. S. Patent No. 5,958,422 are drawn to a species of a method of producing a modified plant virus, and the species makes the genus obvious.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

11. Claims 1, 2, 7-10, 15 and 16 are rejected under 35 U.S.C. 102(e) as being anticipated by US 5,316, 931 (Donson et al.).

US 5,316, 931 (Donson et al.) taught (see especially the abstract and columns 5, 6, 8, 9, 11, 12 and 14) a plant infected with a modified virus comprising modified viral nucleic acid which encoded a foreign peptide which was inserted in sequence coding for a viral coat protein, where there was no significant interference with the capacity of the modified virus to assemble.

The peptide may be an antigen, and the virus may be a comovirus (an RNA virus). Also taught was a method of infecting a plant or plant cell with the modified virus.

Response to Arguments

12. Paper No. 10 asserts that the priority date of the instant application is April 2, 1992, and US 5,316, 931 (Donson et al.) has a filing date of July 31, 1992, making the filing date of US 5,316, 931 (Donson et al.) ineffective for prior art purposes without relying on the teachings of the CIP parent document of US 5,316, 931 (Donson et al.), US Application No. 07/600,244. The parent CIP document Appl. No. 07/600,244 can be relied upon for the following reasons: Appl. No. 07/600,244 recites at pages 12, 28, 34, 36, 39 and examples 17 and 28 for instance, the insertion of a foreign peptide in the coat protein to produce a recombinant plant virus, such a cow pea mosaic virus. Infecting a plant tissue with the recombinant virus. Expressing a mammalian virus protein inserted into the plant virus coat protein. The mammalian virus may be a Rhinovirus, for example. The foreign peptide may be used to produce a immune response. Thus the priority date of US 5,316, 931 (Donson et al.) is the filing date of the parent CIP document US Application No. 07/600,244, October 22, 1990. Therefore, the argument is not found convincing.

13. Claims 1-3, 6-11 and 14-16 are rejected under 35 U.S.C. 102(e) as being anticipated by US Application No. 07/600,244 (Grill et al.).

US Application No. 07/600,244 (Grill et al.) taught (see especially the abstract and pages 27, 28,34, 36-40, 53, examples 17, 27, 28 and 50 and the claims) a plant infected with a modified virus comprising modified viral nucleic acid which encoded a foreign peptide which was inserted in sequence coding for a viral coat protein, where there was no significant interference with the capacity of the modified virus to assemble. The peptide may be from a rhinovirus (which may be an antigen), and the virus may be a comovirus (an RNA virus). Also taught was a method of infecting a plant or plant cell with the modified virus.

Any protein may be used as an antigen. This property of a protein is inherent. (see Harlow and Lane, pages 75-77).

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

15. Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,316, 931 (Donson et al.) in view of US Application No. 07/600,244 (Grill et al.) and US 5,437,976 (Utermohlen).

The claims are drawn to a plant infected with a modified virus comprising modified viral nucleic acid which encoded a foreign peptide which was inserted in sequence coding for a viral

coat protein, where there was no significant interference with the capacity of the modified virus to assemble. The peptide may be an antigen, and the virus may be a comovirus (an RNA virus). Also claimed was a method of infecting a plant or plant cell with the modified virus. The antigen may be from a foot and mouth disease virus, a HIV virus or a human rhinovirus.

US 5,316, 931 (Donson et al.) taught the invention as described above in the rejection under 35 USC 102.

US 5,316, 931 (Donson et al.) did not teach that the antigen was a viral antigen.

US Application No. 07/600,244 (Grill et al.) taught (see especially the abstract and pages 27, 28,34, 36-40, 53, examples 17, 27, 28 and 50 and the claims) a plant infected with a modified virus comprising a nucleic acid which encoded a foreign viral peptide which was inserted into a sequence coding for a viral coat protein. There was no significant interference with the capacity of the modified virus to assemble. The encoded foreign viral peptide may be from a rhinovirus. The foreign peptide may be used to produce an immune response. The plant virus may be a comovirus (an RNA virus). Also taught was a method of infecting a plant or plant cell with the modified plant virus.

US 5,437,976 (Utermohlen) taught (see especially column 4, lines 8-25) the selection of nucleotide sequences which are useful for the development of vaccines. The list of obvious sources for this selection of nucleotide sequences is found in Table 1, which includes foot and mouth disease virus, HIV virus and human rhinovirus.

It would have been obvious to one of ordinary skill in the art at the time of filing the instant application to combine the teachings of US 5,316, 931 (Donson et al.) in view of US Application No. 07/600,244 (Grill et al.) and US 5,437,976 (Utermohlen) to produce the instant invention because US 5,316, 931 (Donson et al.) teaches the insertion of any protein encoding sequence into the coat protein for the use in, for example vaccine production. US Application No. 07/600,244 (Grill et al.) taught the insertion of a foreign viral nucleic acid into the coat protein of a plant virus, where the foreign viral nucleic acid encoded a protein from a rhinovirus. US Application No. 07/600,244 (Grill et al.) taught the production of an immune response with the encoded foreign protein. US 5,437,976 (Utermohlen) teaches the use of any encoded gene for the development of a vaccine, and provides a table of obvious selections including HIV virus, human rhinovirus or Foot and mouth disease virus.

One of ordinary skill in the art would have been motivated to combine the teachings of US 5,316, 931 (Donson et al.) in view of US Application No. 07/600,244 (Grill et al.) and US 5,437,976 (Utermohlen) to produce the instant invention because US Application No. 07/600,244 (Grill et al.) and US 5,316, 931 (Donson et al.) taught the beneficial and desirable insertion of a nucleic acid sequence encoding a foreign protein in a gene encoding a coat protein of a plant virus (for example cow pea mosaic virus) to produce the foreign protein which may then be used for the development of an immune response. US 5,437,976 (Utermohlen) taught that there were many desirable viruses to use to develop vaccines. The desirable viruses are set forth in a table of obvious selections including HIV virus, human rhinovirus or Foot and mouth disease virus.

Thus one of ordinary skill in the art would have been motivated to combine the recombinant plant viruses of US Application No. 07/600,244 (Grill et al.) and US 5,316, 931 (Donson et al.) which are useful in making of vaccines with the desirable and obvious nucleic acids from a collection of obvious viruses provided in the table of US 5,437,976 (Utermohlen) which are useful in providing nucleic acids for the development of vaccines. Further, a person of ordinary skill in the art would have had a reasonable expectation of success in the producing the instant claimed invention given the teachings of US Application No. 07/600,244 (Grill et al.) with US 5,316, 931 (Donson et al.) and US 5,437,976 (Utermohlen).

Conclusion

16. Certain papers related to this application are ***welcomed*** to be submitted to Art Unit 1636 by facsimile transmission. The FAX numbers are (703) 308-4242 and 305-3014. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant *does* submit a paper by FAX, the original copy should be retained by the applicant or applicant's representative, and the FAX receipt from your FAX machine is proof of delivery. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications should be directed to Dr. William Sandals whose telephone number is (703) 305-1982. The examiner normally can be reached Monday through Thursday from 8:30 AM to 7:00 PM, EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached at (703) 305-1998.

Any inquiry of a general nature or relating to the status of this application should be directed to the Zeta Adams, whose telephone number is (703) 305-3291.

William Sandals, Ph.D.
Examiner
August 26, 2002

TERRY MCKELVEY
PRIMARY EXAMINER